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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,431	09/15/2003	David W. Morris	PP023357.0001 /20366-0710	2348

7590 10/09/2007

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,431	MORRIS ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-73* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, and 45-46, drawn to an isolated nucleic acid, host cell, expression vector, a kit comprising the nucleic acids for diagnosing the presence of cancer, classified in class 536, subclass 23.1.

II. Claims 16-21, drawn to isolated peptide encoded within an open reading frame of a CA sequence, classified in class 530, subclass 300 or subclass 350.

III. Claims 22-41, drawn to an isolated antibody, hybridoma, pharmaceutical composition, or a kit comprising antibody, classified in class 530, subclass 387.1.

IV. Claim 42, drawn to an in vitro method for detecting a presence or absence of a cancer cells with antibody, classified in class 435, subclass 7.1 and 7.92.

V. Claim 43-44, drawn to an in vivo method for inhibiting growth of cancer cells in an individual comprising administering to the individual an effective amount of a pharmaceutical composition comprising antibody, classified in class 424, subclass 130.1.

VI. Claims 47-48, drawn to an electronic library comprising a polynucleotide, or its fragment, classified in class 536, subclass 23.1.

VII. Claim 49, drawn to an electronic library comprising a polypeptide, or its fragment, classified in class 530, subclass 300, and 350.

VIII. Claims 50-53, drawn to a method of screening for anticancer activity comprising contacting an anticancer drug candidate to a cell expressing the CA gene and monitoring the effect of the cancer drug, classified in class 435, subclass 7.23.

IX. Claims 54-55, drawn to a method of detecting and comparing the CA polypeptide expression, classified in class 435, subclass 4, class 436, subclass 536.

X. Claims 56, drawn to a method of detecting and comparing the levels of CA polypeptide antibody (autoantibody) a test serum sample, classified in class 436, subclass 512, class 435, subclass 7.1, and class 424, subclass 130.1.

XI. Claims 57-60, drawn to a method for screening for a bioactive agent capable of modulating the activity of a CA protein, classified in class 435, subclass 7.23.

XII. Claim 61, drawn to a method of diagnosing cancer comprising determining the gene expression on the CA gene comprising by determining the RNA expression, classified in class 436, subclass 6.

XIII. Claims 62-70, drawn to a method of treating cancers comprising administering to a patient an inhibitor of CA protein, classified in class 514, subclass 1 (see note on next page).

XIV. Claims 71-73, drawn to a method of inhibiting expression of a CA gene in a cell by contacting a cell with a double stranded RNA that hybridize to a CA mRNA, classified in class 514, subclass 44.

Further election:

Applicants elect any one of the groups set forth above, further restriction is required under 35 U.S.C. 121:

Elect ONE single SEQ ID NO listed either in the claim(s) of the elected group or elect One single SEQ ID NO listed on table 1-15.

The restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences or more than one unrelated SEQ ID NO in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect ONE from Groups I- XIV and ONE SEQ ID NO even though the requirement is traversed. Applicant is advised that neither I-XIV nor SEQ ID NO is species election requirements; rather, each is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

In addition, applicant is noted that once the SEQ ID NO for invention XIII is elected, the inhibitor for the protein having the elected SEQ ID NO would be limited to the elected protein. Thus, the claims drawn to the method using an inhibitor for the other protein would be withdrawn from the consideration.

Inventions are distinct each from the other because of the following reasons:

Inventions I-III, VI, and VII are patentably distinct products for the following reason:

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence. open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I does not necessarily encode a polypeptide of group II. Similarly, the nucleic acid molecule is complementary to the coding sequence, and therefore would not encode the polypeptide of group II. Furthermore, the information provided by the polynucleotide of group I can be used to make a materially different polypeptide than that of group II. In addition, while a

polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

The polypeptide of Group II and the antibody of Group III are patentably distinct product. While the inventions of both Group II and Group III are polypeptides, the polypeptide of Group II is a single chain molecule, whereas the polypeptide of Group III encompasses antibodies including IgG, which comprises 2 heavy and 2 light chains containing constant and variable regions. Thus the polypeptide of Group II and the antibody of Group III are structurally distinct molecules; any relationship between the polypeptide and the antibody is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. The antibody of group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The other groups, electronic library of polynucleotide, or library of polypeptide are patently distinct products, which are drawn to a combination of detectable probes having the properties as stated above. The inventions have a separate status in the art as shown by their different classifications. Searching more than one the invention groups are not coextensive, which would impose a serious search burden.

Inventions III and IV, III and V, III and IX, III and X are related as product (antibody III) and process of use (IV-V and IX-X). Inventions group I and XII are also related as product (nucleic acid) and process of use (XIV). The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used to detect the CA protein expression in cancer cell in group IV, as opposed to being used as administering for treating a cancer in group V. Further, inhibiting the cell growth group V may be achieved by use nucleic acid to inhibit the protein production instead of inhibition the function of the protein as stated in group V.

Inventions IV-V and VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods using different active ingredients that have different functions or drawn to methods using the same materials for different process that have different mode of operation. For example, although group IV and V are drawn to a method of detection, inhibition, or delivering a therapeutic agent using an antibody to CA protein, each method has different method objective, which are involved in different method steps and mode of operations. Each method may also require different patient population or biological samples from different patients. Another example, the methods of group V, XIII, and XIV are drawn to treating cancers or inhibiting CA gene expression, which all use different materials (antibody for group V, small molecule for group XIII, and double strand RNA for group XIV) to operate. Because each invention group either requires different materials or have different method steps or objectives, the searching of all the methods are not co-extensive in non-patent literature and US patent database, which would impose a serious search burden.

Because these inventions are distinct for the reason given above and have acquire a separated status in the art by their different classification, restriction for examination purpose as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37

CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitation of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitation of an allowable product claim for that process invention to be rejoined.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution to require the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SUSAN UNGAR, PH.D
PRIMARY EXAMINER